

The Potential Demand for and Strategic Use of an HIV-1 Vaccine in Southern India

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Abstract

Even a modestly effective HIV-1 vaccine would be highly useful in India and could avoid millions of deaths. How should such a vaccine be introduced? Based on evidence of adoption of other vaccines in India, current levels of spending on them and coverage of prevention programs targeting both high- and low-risk groups, Seshadri, Subramaniam, and Jha assess the potential demand for and strategic use of an HIV-1 vaccine in the four southern Indian states of Andhra Pradesh, Karnataka, Maharashtra, and Tamil Nadu. The authors also discuss potential strategies for delivery of the vaccine, prioritization for vaccination, and the political economy of such a vaccine in India. Assuming a vaccine cost of \$10 a dose and including estimated delivery costs, the total cost of vaccinating 21.6 million adolescents 11–14 years of age and 1 percent of adults would be Rs. 12.25

billion (US\$ 245 million). To maintain the vaccination rate in the 11–14 year old cohort, an additional 6.77 million in that age range would have to be vaccinated each year, at a vaccine cost of Rs. 3.39 billion (US\$ 67.5 million).

An HIV-1 vaccine will greatly reduce HIV/AIDS in India, but it will not be a panacea. There will be a continued need for effective prevention programs to guard against behavior reversals or an imperfect vaccine. Key inputs for prevention, immunization, and treatment programs such as identification of various groups that could be immunized (vulnerable groups or general populations), strengthened surveillance, capacity building, operations research, and evaluation at local levels will continue to require intensive support.

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Acronyms

ANC	Antenatal clinic
CMH	Commission on Macroeconomics and Health
CSW	Commercial sex workers
DFID	United Kingdom Department for International Development
EPI	Expanded program of immunization
HbsAg	Hepatitis B surface antigen
HBV	Hepatitis B Virus
HIV	Human immunodeficiency virus
ICMR	Indian Council for Medical Research
MSM	Men who have sex with men
NACO	National AIDS Control Organization
PLWHA	People living with HIV/AIDS
RCH	Reproductive and child health
STI	Sexually-transmitted infection
USAID	United States Agency for International Development

1. Introduction

This paper assesses the potential demand for and strategic use of an HIV-1 vaccine in southern India.¹ The paper assesses the size of potential high- and low-risk target groups for an HIV-1 vaccine in the 117 districts of Andhra Pradesh, Maharashtra, Karnataka, and Tamil Nadu. It also discusses potential strategies for delivery of the vaccine, prioritization for vaccination, and the political economy of such a vaccine in India. The latter issue includes a discussion of the current level of knowledge and existing level of stigma as barriers to demand for a vaccine, even if it were offered free of charge. In reviewing these data, the paper draws from examples of coverage of prevention programs targeting both high- and low-risk groups, of adoption of other vaccines in India and current levels of spending on them. An HIV-1 vaccine will greatly reduce HIV/AIDS in India, but it will not be a panacea. There will be a continued need for effective prevention programs to guard against behavior reversals or an imperfect vaccine.

2. The HIV-1 Epidemic in Southern India

The Indian government estimates that in 2000, 3.86 million Indians were living with HIV-1, the second largest number of infected people after South Africa (NACO 2000). While HIV is transmitted via all major modes of transmission in India, the engine of the Indian epidemic is heterosexual transmission from vulnerable groups,² chiefly commercial sex workers and their clients. The prevalence of HIV-1 in India may seem relatively low, at 0.7 percent of the general adult population, compared with rates of 20 percent and higher in Botswana, South Africa, and Zimbabwe. Nevertheless, HIV has now been detected in all states and union territories. It has spread from sex workers and transport workers to women in the general population, and from urban to rural areas. If effective prevention efforts are not implemented and sustained over the long term, mathematical models suggest that India could have over 30 million people infected by 2010 (Nagelkerke and de Vlas 2003).

The four southern states of Andhra Pradesh, Karnataka, Maharashtra, and Tamil Nadu account for nearly two-thirds of all HIV infections in India, even though they have less than 30 percent of the total population (Table 1). These four states have among the highest infection rates: a median of 1.3-2.2 percent of women attending antenatal clinics and 14-24 percent of patients attending public facilities for the treatment of sexually-transmitted infections (STI) are infected with HIV-1.

¹ Throughout the text, we refer to HIV-1 as this is the most common in India and research on differences between HIV-1 and HIV-2 is at an early stage in India (Sahni and others 2002).

² Vulnerable groups are defined as those who, because of risky sexual behavior, are at increased risk of acquiring and transmitting HIV-1 infection. Chiefly, this refers to female sex workers, and their male clients, as well as to injecting drug users where relevant.

Table 1. Population and HIV-1 Prevalence in Southern India

State	Population in millions (2001)	Estimated number of HIV-1 infected adults (1998)	Median HIV-1 prevalence (1998)	
			Antenatal clinic attendees	Sexually transmitted disease clinic attendees
Andhra Pradesh	75.7	950,000	2.18	22.71
Karnataka	52.7	430,000	1.75	14.38
Maharashtra	96.7	790,000	2.23	24.03
Tamil Nadu	62.1	300,000	1.31	15.84
Southern states	288.5	2,470,000	1.93	20.05
India	1027.0	3,860,000	0.90	9.45

Source: Author's calculations based on NACO data for the 2001 Population Census and 1998 National Sentinel Surveillance data. More recent antenatal clinic (ANC) data suggest lower infection levels, especially for antenatal clinic attendees. Given ANC data could well under- represent prevalence (Thomas and others 2002), we have used the earlier higher figures.

The development of a safe and effective preventive AIDS vaccine is becoming a global health priority, particularly in the developing world where HIV is spreading most rapidly. Recent modeling of the impact of an HIV/AIDS vaccine in southern India found that a vaccine that confers 100 percent protection for a lifetime in 95 percent of all vaccine recipients could almost eradicate HIV-1 within 25 years (Nagelkerke and de Vlas 2003). The impact of a highly effective vaccine would be high, even if commercial sex workers (CSW) and their clients discontinued condom use ("disinhibition"). If high-risk populations were targeted with such a vaccine and assuming disinhibition, adult HIV-1 prevalence in southern India in 2033 would reach 1.4 percent, while it would rise to 2.1 percent if the general population were targeted.³ On the other hand, a vaccine that confers 50 percent protection in 50 percent of recipients would have less of an impact and preventing disinhibition would be key. Assuming no disinhibition, adult HIV-1 prevalence would reach 3.7 percent in 2033 if high-risk groups are targeted with this less-effective vaccine, and 4.6 percent if the general population is targeted. The effects of this less-effective vaccine could be reversed by disinhibition, with adult HIV-1 prevalence in 2033 of 10.3 percent if high-risk groups are targeted with the vaccine and 10.0 percent if the general population is targeted.

A brainstorming session on HIV-1 vaccine development by India was held in New Delhi in November 1998 among scientists working on an HIV-1 vaccine in India and abroad (World Bank 1999). All of the experts were of the view that India should initiate a program on HIV-1 vaccine development in collaboration with international scientists, keeping in view the various aspects of clinical trials and ethical issues. Subsequent meetings have resulted in the drafting of a Memorandum of Understanding between the International AIDS Vaccine Initiative and the Government of India represented by the Indian Council of Medical Research (ICMR) and the National AIDS Control Organization (NACO) for accelerating development

³ Nagelkerke and de Vlas (2002) assume that in the absence of a vaccine adult HIV-1 prevalence would reach 5 percent by 2033.

of an AIDS vaccine applicable for use in India (IAVI website:
http://www.iavi.org/highlights/82/oldH2001-03-20_India_VDP_Launch.htm).

3. Experience with Other Vaccines in India

The experience of the implementation of the routine childhood immunization program in India provides valuable lessons for the introduction of an AIDS vaccine. Even though early generation HIV-1 vaccines may not be suitable for use with children under five, the coverage and service delivery modalities help in understanding the scope of the challenge of introducing a new vaccine in the Indian context.

India started with a Universal Immunization Program for children under 5 years of age in the 1970s, then went on to a phase of the Expanded Program of Immunization (EPI), which has become a part of the Reproductive and Child Health (RCH) program. The RCH program includes not only immunization against the six vaccine preventable diseases for children,⁴ but also tetanus toxoid for adolescent girls and pregnant women. It further includes some experiments with neo-natal tetanus and hepatitis-B immunization in Andhra Pradesh state.⁵

The Indian Academy of Paediatrics has advocated the use of hepatitis B vaccine as part of the routine immunization schedule. Many doctors in the private sector, therefore, do administer hepatitis B vaccine to patients and children under their care. In addition, several schools and non-governmental organizations have been organizing hepatitis B vaccine drives on a payment basis. However, this vaccine has not yet reached the poorer populations, whether urban or rural. The Government of India does support planned state programs for the introduction of the hepatitis B vaccination as part of the routine immunization program. The states of Kerala, Haryana, Delhi, and Andhra Pradesh are all piloting hepatitis B, with the largest coverage (about a third of the state) in Andhra Pradesh.⁶ During the recent past, hepatitis B vaccine has been generally available in the private sector hospitals in the urban areas to those who can afford it.

A key lesson from a review of the addition of new vaccines like Hepatitis B and Haemophilus influenza type b in Asia suggests that strengthening routine immunization programs can raise the coverage for newer vaccines and that introduction of newer vaccines can stimulate broader coverage of existing immunization programs (Olivera-Cruz and others

⁴ BCG, Diptheria-Pertussis-Tetanus (DPT), OVC, measles.

⁵ India has hepatitis B surface antigen (HbsAg) prevalence between 2 and 10 percent among the populations studied and prevalence does not vary significantly by the different regions of the country. More than 40 million Indians are estimated to be carrying HbsAg. Of the estimated 25 million babies born every year, over one million run the lifetime risk of developing chronic hepatitis B virus (HBV) infection. Estimates also indicate that annually over 100,000 Indians die due to illness related to HBV infection (Lodha and others 2001).

⁶ The Government of Andhra Pradesh's Partnership Project for hepatitis B vaccine and strengthening of routine immunization with the Children's Vaccination Program of Program for Appropriate Technology in Health (PATH).

2001). For example, routine immunization coverage rose in Thailand after Hepatitis B vaccination was introduced. Reviews have also found that successfully adding a new vaccine is predicated on having reasonable coverage of existing vaccines.

In India, adoption of different EPI vaccines is a joint decision of national and state governments. In 1999-2000, total GOI recurrent EPI expenditures amounted to Rs. 2,070 million (about US\$ 42 million). (MOHFW 2001). Of this, about 47 percent, or Rs. 978 million (US\$20 million), was spent on vaccines, about 30 percent, or Rs. 634 million (US\$ 13 million) on salaries of staff, about 14 percent, or Rs. 308 million (US\$6.3 million) on maintenance (including cold chain), and the rest for transportation costs and awareness building.

4. Assessing the Size of Potential Target Groups for an HIV Vaccine

The following section estimates the size of target groups for a public HIV-1 vaccination program in both high-risk groups and the general population. We assume that one strategy for delivering the vaccine would be to piggyback an HIV immunization program on existing programs to reach different groups. Thus, the section also examines the levels of coverage of existing HIV-1 prevention interventions for high-risk groups and the general population in the southern states, highlighting the gaps in coverage.

Analysis shows that targeting high-risk groups with a vaccine is much more cost-effective than targeting the entire adult population, regardless of risk (Nagelkerke and de Vlas 2003). At approximately one third of the number of vaccines needed, a higher reduction in prevalence is achieved. However, this would depend on the type of vaccine developed. Early vaccines may be less than fully effective and of unknown duration. In that case, the vaccine may at best delay infection of high-risk groups and it would be more effective for government to promote condoms and behavior change interventions. On the other hand, highly effective vaccines could potentially be targeted to CSWs only. Vaccinating the general population or clients of CSWs would be less necessary, although it would protect clients against infected CSWs, and the general population from clients who are already infected.

Table 2 presents estimates of the size of potential high- and low-risk groups who could be targeted for a preventive HIV-1 vaccine in southern India. Estimates of the number of sex workers in the four states are in the range of 690,000-870,000 and the number of truck drivers roughly double that number. In contrast, the number of sexually transmitted infection (STI) patients in the four states in 2001 was only on the order of 165,000. The four southern states account for about 36 percent of the total STIs recorded in the country at public facilities (see Annex Table 1.3). However, this is a severe underestimate of the true number of persons with STIs in the population, as more than half of those with symptomatic STIs self-treat or consult private care and others have asymptomatic infections (often the case with women) and thus do not seek treatment. Reliable data on the incidence and prevalence of STIs is limited, mainly due to the inadequacy of the surveillance system (Hawkes and Santhya 2001). NACO

estimates that the annual incidence of STIs is 5 percent of the adult population, which implies that about 7 million new STI cases are occurring annually in the southern states. There is very likely some overlap between the STI patients at government clinics and other high-risk groups, but government clinics with STI services is clearly one way that government can access these groups. A strategy that focused on vaccinating these three high-risk groups in the four states might therefore require on the order of 2.6 million doses of vaccine.

Table 2. Estimates of the Number of Individuals in Potential Target Groups for a Preventive HIV-1 Vaccine, Southern India

State	High-risk groups →				Low-risk groups →				
	CSW- low estimate	CSW- high estimate	Truck drivers	STI patients	Population 0-6	Population 11-14	Adults 15-49	Women of reproductive age	Antenatal clinic attenders
Andhra Pradesh	184,208	203,000	358,422	27,353	9,673,274	8,955,850	37,121,289	18,504,177	1,483,538
Karnataka	127,318	162,000	266,724	23,537	6,826,168	6,212,630	25,903,503	12,554,834	952,721
Maharashtra	228,376	292,000	525,867	46,947	13,187,087	11,416,766	47,602,107	22,930,801	1,805,679
Tamil Nadu	151,744	212,000	457,131	66,694	6,817,669	7,258,282	30,263,333	15,236,042	1,314,874
TOTAL	691,646	869,000	1,608,144	164,531	36,504,198	33,843,528	140,890,232	69,225,534	5,556,813

Source: CSW: Low estimates are calculated as 1.5 percent of the total female population aged 15-49. High estimates are based on Venkataramana and Sarada (2001). Truck drivers: Assumes three drivers for every registered truck in the state in 1997, based on SIAM (1999). STI patients: Based on GOI data on STI clinic attendees at public facilities. Population 0-6, 10-14, adults 15-49, women of reproductive age: 2001 Census of India. Antenatal clinic attenders: Based on NFHS 1992, drawing on the crude birth rate and the percent who have at least two tetanus injections in pregnancy.

While vaccination of low-risk populations will not prevent many secondary infections, if the vaccine is extremely inexpensive to deliver to low-risk groups (relative to delivery to high-risk groups) and/or if there are risks of inhibition among high-risk groups that will reduce the impact of vaccination, then vaccination strategies might target low-risk populations. If resources were available to vaccinate all adults 15-49, then 141 million doses would be necessary. However, it isn't clear how this entire population could be reached. There are more accessible sub-sets of the low-risk population – children under six, adolescents in the 10-14 age group, and women attending antenatal clinics. Current coverage of immunization for children is the base upon which an HIV vaccine could be introduced. This would require about 45 million doses, assuming a single dose per child and current coverage of 83 percent (see Table 3). Similarly, about 5 million women in the four states attend ANC clinics. But coverage is lower at 76 percent. Reaching all ANC women would require about 7 million doses

The estimates in Table 2 represent the size of the total unvaccinated population of different groups, were the vaccine introduced in 2002. Once the initial groups are covered, the HIV vaccination program will require only sufficient vaccine to 'maintain' coverage levels as individuals join the cohort or group.

The estimates in Table 2 are high-end estimates because it is doubtful that everyone in a given target group could be reached. If the HIV vaccine were distributed via a strategy of piggybacking on existing health interventions, then the coverage of those other interventions or programs provides an alternative estimate of the number of people who could actually be reached. Estimates of estimated levels of coverage of the target populations with current HIV prevention and other services that might serve as conduits for vaccine delivery are in Table 3. Current coverage of high-risk groups with programs is relatively low—less than a third—while the coverage of many of the low-risk groups (young children via EPI and antenatal care) is relatively high—better than 70 percent. This underscores the point that unless coverage of high-risk groups with other interventions is expanded, an HIV vaccination campaign might have limited access to those most vulnerable to infection.

Table 3: Percent of the Potential Target Groups for an HIV-1 Vaccine Covered by HIV Prevention and Other Programs, Southern India

<i>State</i>	<i>Sex workers^a</i>	<i>Truck drivers^a</i>	<i>STI patients^b</i>	<i>EPI^c</i>	<i>MWRA^d</i>	<i>ANC</i>
Andhra Pradesh	12-14	31	33.6	75.7	0.7	74.8
Karnataka	7-9	15	20.9	91.3	1.0	69.8
Maharashtra	5-7	12	34.3	79.5	4.0	71.0
Tamil Nadu	16-22	33	31.4	91.9	1.5	90.1
Total/Average	10-12	23	30.5	83.0	2.0	76.0

a. Percent of group that is currently reached by targeted HIV prevention interventions.

b. Percent of those with an STI in the past 12 months who were treated at a government hospital or clinic, from the 2001 national Behavioral Surveillance Survey (BSS). Note, however, that the sample size of persons reporting an STI was small (ranging from 59 in Tamil Nadu to 288 in Andhra Pradesh), so these estimates are not precise.

c. Percent “fully immunized”, with BCG, DPT (3 doses), OPV (3 doses), and measles.

d. Percent of married women of reproductive age (MWRA) who are using condoms for contraception.

Source: See calculations and sources in Annex 1.

5. Strategic Use of an HIV-1 Vaccine

Currently, in the absence of a vaccine, the prevention strategy is based chiefly on interventions that reduce cascade transmission among and from vulnerable risk groups (Jha and others 2001, Brunham and Plummer 1990). Each infection prevented among sex workers prevents “downstream” consequences. Vulnerable-group interventions involve peer-based education of sex workers, their clients and others at high risk (e.g. truck drivers) in the use of condoms, negotiation skills and treatment of STIs. Worldwide experience has found these interventions to be effective.

The HIV-1 vaccine could be delivered either by using the model established by the EPI program, for example, if it is to be targeted to the general population; or by piggybacking on other interventions to reach high-risk groups; or on some combination of these two methods. The vaccine could be made available through the government health care network. In this case, ensuring access to vaccination sites and consistent availability of services are important considerations. Table 4 summarizes delivery strategies for reaching specific low-

and high-risk populations with an AIDS vaccine, the size of the groups in southern India, the coverage of the programs, and the strengths and weaknesses of targeting each group via the proposed strategy.

Delivery strategies for the general (low-risk) population

If the vaccine were to be targeted to the general population, then it is useful to look at other programs targeted to this group and how they have performed. Whether the HIV-1 vaccine is administered to newborns or to pre-pubescent youth, lessons could be learned from one of the programs described below in terms of strategies that might be appropriate for dissemination of such a vaccine.

Children under six: Expanded program of immunization. The EPI has a well articulated service delivery network within the public health care system and is provided at all government health facilities: hospitals, primary health centers and sub-centers. In addition to immunization provided at all times to those who attend the health facility, the routine immunization program uses a fixed place and time strategy for outreach. In rural areas, the area covered by a sub-center is divided into four sub-sectors. A UNICEF cluster survey (1997-98) found that about 80 percent of all children between 13-24 months of age were within half a kilometer distance of a scheduled session site. Each sub-sector is served by the sub-center itself, and an outreach session (camp) is planned each month at a selected site on a fixed day of the week. In remote rural areas, a camp approach is used, with health staff and vaccines visiting the area regularly for a three-month cycle twice a year. In the case of the pulse polio immunization campaign, the entire primary health care network is mobilized twice a year, with the necessary infrastructure and supplies carefully planned, to deliver services across the country.

The campaign approach may not be appropriate or feasible for an HIV-1 vaccine, however. Even with a universally accepted program such as polio eradication, there is considerable “camp fatigue” that has set in after 4 years of the pulse polio immunization campaign. In the case of an HIV-1 vaccine, with the social stigma associated with HIV/AIDS, it is likely that the resentment against such campaigns would be even more acute. A much more appropriate method for reaching vulnerable populations would be to use existing intervention programs as an outreach vehicle.

Table 4. Delivery Strategies for an HIV-1 Vaccine in Southern India to Target Populations

Target population	Size of group	Ongoing government program	Coverage of ongoing program	Strengths and weaknesses
<i>Low-risk groups</i>				
Children under six	36.5 million	EPI	83%	<i>Strengths:</i> High coverage; most children are HIV-negative, so little wastage of vaccine. <i>Weaknesses:</i> If vaccine is of short duration, will not protect children into adulthood and will have limited impact on the epidemic. Even if lifetime duration, impact on the epidemic will be delayed until they reach adulthood. The vaccine program may be less efficient because, few secondary infections are averted per injection, on average.
Children 11-14	33.8 million	School plus outreach program	Only about 46% of all kids in school	<i>Strengths:</i> Reaches adolescents shortly before they become sexually active; even a vaccine of less than lifetime duration will have an impact <i>Weaknesses:</i> Limited access to these children except through the school system (but enrollment rates are low) or by community campaigns. A short duration vaccine may not protect them during their most sexually active years. Also possibly not efficient (see above).
Pregnant women	5.6 million	Antenatal clinics	76%	<i>Strengths:</i> High coverage, reaches women who are sexually active, vaccination of HIV-negative mother will prevent transmission to future children.. <i>Weaknesses:</i> Target group is generally low risk, preventing few secondary infections. One quarter of women not reached, possibly those most at risk.
<i>High-risk groups</i>				
CSW	869,000	Targeted HIV interventions	10-12%	<i>Strengths:</i> Efficient, as many secondary infections averted. <i>Weaknesses:</i> With a less than fully effective vaccine and if condom use declines with vaccination, epidemic could get worse. Optimum efforts needed to prevent 'disinhibition'. Stigmatized groups are difficult to reach. Targeted intervention has low coverage at present. Expanding coverage will require capacity building of NGOs.
Truck drivers	1.6 million	Targeted HIV interventions	23%	<i>Strengths:</i> Same as CSW. In particular, will prevent secondary infection of spouses and children. <i>Weaknesses:</i> Same as CSW.
STI patients	164,531	Public STI treatment	30%	<i>Strengths:</i> A good access point for people from all walks of life who are at high risk of contracting HIV and for some, of spreading it. <i>Weaknesses:</i> Public sector clinics have limited coverage; many patients self-treat or seek private care. Strategy for involving the private sector might be necessary.

Children 11-14: School plus outreach programs. Vaccinating children in the 11-14 age group has the advantage of reaching adolescents shortly before they become sexually active; even a vaccine of less than lifetime duration will have an impact. However, access to these children is limited to school-based programs or community campaigns. There is also a possibility that a short duration vaccine may not protect them during most sexually active years. Notwithstanding this, if vaccinating children 11-14 is promoted as a strategy, then the following issues need to be considered.

India has steadily raised primary enrollment rates since independence and today has the world's second largest education system after China, with 148 million children aged 6-14 attending primary school in 1997-98 (MOE 2003). Of these, 39.5 million children are in the upper primary, or 11-14, age group. However, more than 25 million Indian primary school-age children are not in school. Two out of five first-grade students will not complete the primary cycles of 4 to 5 years (depending on the state), and the learning achievement of those graduating is low. In addition, dropout rates are high: the total dropout rate at primary level for all of India is 39.6 percent, while at upper primary level the rate is even higher at 54.4 percent. The dropout rates for girls are higher--41.3 percent and 58.6 percent, respectively. Children from poorer families are at a greater disadvantage. The dropout rate for the poorest households is about four times that of the richest ones. There are large gaps in access to education; quality of education; and learning according to gender, social class, and location. Even so, with a retention rate at school for children 11-14 of about 46 percent, opportunities for providing school-based interventions for this cohort group are substantial.

Pregnant women: Antenatal clinics. There are about 26 million births annually in India, or about 5 million in the four Southern States. The best measure of antenatal care is the percent that have two tetanus shots in pregnancy. This ranges from 71 to 90 percent in the southern states and is lower elsewhere (IIPS 2000). Likely the highest risk women do not go to ANCs. An HIV vaccine could be potentially added to the Integrated Child Development Scheme (ICDS). An earlier study found that complete immunization with tetanus toxoid was recorded for 68 percent of the mothers in the those enrolled in the ICDS program but much lower at 40 percent for those not enrolled. Coverage was greater in the urban and lower in the tribal projects. Scheduled castes, scheduled tribes, backward communities, and minorities (groups that have a high priority for social services) had immunization coverage in enrollment areas that were similar to those of higher castes (Tandon and Gandhi 1992).

Delivery strategies for high-risk groups

Sex workers and truck drivers: Targeted HIV interventions. Targeted interventions comprise a package that includes behavior change communication, condom promotion, STI treatment and creating an enabling environment. NACO and bilateral donors fund between 20 and 114 interventions per state, implemented by nongovernmental organizations (NGOs), that target higher risk people in each of the Southern states. But geographic coverage remains

limited, often to just a few districts in each state. Tamil Nadu, with a very active State AIDS Control Society and the USAID-funded AIDS Prevention and Control (APAC) project, has the widest geographic coverage of targeted interventions, but they still are not present in all 30 districts. Until recently, the red-light areas of Mumbai had only two NGOs covering about 3,000 out of 60,000 sex workers. Even with expansion, well over half of sex workers remain outside of NGO programs. Such interventions also lack technical support, operational research, monitoring and evaluation and training to ensure high *quality* as well as high coverage. Tamil Nadu is a partial exception, and has achieved relatively high coverage of enrolled sex workers and truck drivers; HIV-1 levels appear to show some attenuation (Ramasundaram and others 2001).

STI patients: Health services. Due to the low coverage of government-run STI clinics (about 30 percent coverage only), NACO has initiated Family Health Awareness Campaigns (FHAC) with the objectives of: (i) making people aware of government services available for the treatment of STDs; (ii) facilitating early detection and prompt treatment of STDs; and (iii) strengthening the capacity of medical and paramedical professionals in the health care system to respond to the HIV epidemic. So far, in the southern states, the FHAC has accomplished the following (Table 5).

Table 5. Populations Reached by the Family Health Awareness Campaign, 2001

States	Target population (1)		No. of attendees (2)		(2)/(1)		No. of cases referred		No. of cases treated	
	Males	Females	Males	Females	M	F	Males	Females	Males	Females
Andhra Pradesh	16,334,070	16,621,408	1,532,123	2,333,584	9	14	77,256	181,346	77,480	340,272
Karnataka	10,105,594	9,972,361	1,210,268	1,589,525	11	16	83,670	178,873	37,432	137,339
Maharashtra	8,281,381	7,992,458	828,138	2,157,964	10	27	36,2161	557,802	15,375	90,013
Mumbai	1,818,508	1,793,281	87,610	86,916	4	4	450	404	674	2,980
Tamil Nadu	11,837,949	11,829,270	168,819	665,641	1	5	1,994	12,562	1,774	6,641

Source: Data provided by the State AIDS Control Societies.

STD surveillance through syndrome-based information from peripheral health institutions under the primary health care system and etiological information from STD clinics is due to be introduced, but neither this nor other forms of STI surveillance has yet started (Hawkes and Santhya 2002).

6. The Costs of an HIV Vaccination Intervention in Southern India

The cost of the vaccine product mostly reflects fixed costs (R&D and establishing manufacturing capacity); the greater the volume of vaccine procured the lower the unit cost should be. This will make new vaccines even more affordable for poorer countries. In addition, ensuring that “new” vaccines are actually purchased and included in immunization programs will send a strong signal to researchers and manufacturers that future vaccines they develop will have a market with effective demand (Batson and Ainsworth 2001; Loevinsohn 1999).

In estimating the cost of implementing a publicly-financed HIV-1 vaccination program, we have assumed the following:

- The vaccine would be delivered in a single dose
- It would not require refrigeration
- It would not confer any benefits to those already infected, but would not be harmful
- The cost of the vaccine is Rupees (Rs.) 500 (US\$ 10) per dose
- At the time that the vaccine is introduced, 1 percent of the 15-49 age group (1.41 million adults at high risk and 80 percent of all children aged 11-14 (21.6 million) would be vaccinated. This would be in line with the current level of coverage of the EPI in the four southern states, and would reflect the combined outcome of school-based and outreach programs.
- Maintaining vaccination rates in these two groups would require vaccination of all entrants to the 11-14 year old cohort/year – in other words, all children turning age 11. We estimate that this is roughly one-fourth of the existing 11-14 cohort (6.77 million children).
- We are making no assumptions about the duration or effectiveness of the vaccine, and assume no wastage and that the potential vaccinees would be willing to be vaccinated—an assumption we revisit in the next section.

The total cost of 21.6 million doses of this vaccine for all adolescents age 11-14 and 1 percent of adults would be Rs. 11.5 billion (US\$ 230 million), assuming a vaccine cost of \$10/dose. We estimate that the costs of administering the vaccination program in the four states would be equivalent to half of the annual cost of administering the polio eradication program (Rs. 750 million, or US\$ 15 million), since polio is administered in 3-doses and requires a cold chain, while the HIV vaccine discussed here is a single dose and does not require refrigeration. The delivery strategy would be similar to the polio program, with a combination of fixed facility and outreach programs. It should be pointed out that these estimates are extremely rough, and would likely underestimate costs quite substantially, since certain fixed costs such as establishment costs, training costs, salaries and so on are not included. The costs are confined to incremental costs associated with administering the vaccine. **Thus, the total cost of the initial vaccination (“catch up”) of these groups in the four southern Indian states is estimated to cost Rs. 12.25 billion (US\$ 245 million).** To maintain the vaccination rate in the 11-14 year old cohort, an additional 6.77 million 11-year-olds would have to be vaccinated each year, at a vaccine cost of **Rs. 3.39 billion (US \$67.5 million).**

Table 6. Estimated Cost of HIV Vaccines and Additional Costs to Scale-up Prevention Activities

<i>Intervention</i>	<i>Level of coverage assumed</i>	<i>Rupees (millions)</i>	<i>US dollars (millions)</i>
<i>HIV vaccine</i>			
Initial vaccination (first year)	80% of children 11-14, 1% of adults 15-49	12,250	245
Recurrent (maintenance) ^a	100% of children turning 11 (estimated at 25% of the 11- 14 cohort)	3,390	67.5
<i>Vulnerable group interventions</i>			
CSWs (annual)	100% coverage	966.8	19.3
Truckers (annual)	100% coverage	118.4	2.4
<i>STI treatment</i>			
	Build up to maximum of two STI treatment centers per district		
Initial investment		92	1.8
Annual recurrent cost		56	1.1
<i>Sentinel surveillance</i>			
Annual	Achieve one sentinel site per district ^b	7	0.13
Total			
Investment ^c		13,434.2	268.6
Recurrent ^d		4,538.2	90.4
<i>Condom promotion</i>			
Recurrent ^e	100% condom use by all men 15-49, within and outside marriage	27,000	540.6
Total with condom promotion			
Investment		40,434.2	808.2
Annual		31,538.2	631.0

Note: a. Includes the cost of vaccines only; delivery costs not included.

b. Requires building 59 additional sites; this includes investment and recurrent costs.

c. Assumes that investment would be at least equal to the recurrent costs for interventions for vulnerable groups and sentinel surveillance. However, it excludes additional capacity building and other start-up costs for vulnerable group interventions.

d. Assumes that sentinel surveillance figures are recurrent.

e. Costs of additional condoms only. Assumes that the public sector finances all of the costs of the shortfall in condom use. In fact, a high share of condoms currently used in India is purchased privately through social marketing.

As noted earlier, because of the possibility of using other channels of preventive interventions for delivering an AIDS vaccine, the risk of reversals of other preventive behaviors (disinhibition) with a less than fully effective vaccine, and the complementarities among interventions in increasing knowledge and reducing stigma, introduction of an HIV-1 vaccine would have to occur in parallel with a scaling up of other preventive interventions and of sentinel surveillance. Table 5 summarizes the costs of an AIDS vaccine and total costs of "scaling up" these other HIV preventive interventions in the four states – the vulnerable group interventions for sex workers and truckers, STI treatment, and HIV sentinel surveillance. These estimates, for which the calculations are detailed in Annex 2, are extremely rough and do not include certain fixed costs such as start-up costs, training costs, salaries and so on. The costs are confined to incremental investment and recurrent program costs of the *additional*

interventions necessary for the specified coverage and do not include the recurrent costs of maintaining existing prevention activities.

The investment costs of introducing an AIDS vaccine (under the assumptions made) and achieving full coverage of vulnerable groups, STI treatment, and sentinel surveillance works out to an additional US\$0.93 per capita and the recurrent costs to an additional US\$ 0.32 per capita per year. This is substantially higher than the US\$0.02 – US\$0.04 currently being spent in these states, but the current programs do not include an AIDS vaccine and the coverage of the existing interventions is low (Jha and Mills 2002) If one were to add the objective of universal condom use by men in sex within and outside marriage, then the total investment costs rise to US\$2.80 per capita and the recurrent cost to US\$2.18/capita/ year – assuming that it is entirely financed by the government.⁷

The key point from such costing efforts is that a relatively large increase in spending over current levels is required, even if the vaccine cost is as low as Rs. 500 (US\$10). It will require considerable political will to make this quantum leap in funding, as well as considerable assistance from bilateral and multilateral donors. In Andhra Pradesh and Karnataka, the current leadership is very keen on tackling the epidemic effectively and making a difference. The Chief Minister of Karnataka, Mr. S.M. Krishna, has personally taken over as the Chairman of the Karnataka AIDS Prevention Society. Such leadership needs to be supported with adequate epidemiological information and programmatic guidance to be able to make the necessary financial commitment.

7. Key Constraints to Introducing an HIV Vaccine and Scaling-up Prevention

Stigma. Unless the stigma associated with HIV/AIDS in India can be reduced, few individuals will be willing to be vaccinated and the successful expansion of other preventive interventions to high-risk groups will be jeopardized. HIV/AIDS-related stigma and discrimination are most closely related to sexual stigma, since it deals with the sexual behavior of persons who are considered to be different from the “norm” (Population Council 2000). It is also strongly linked to gender-related stigma: female sex workers are often stigmatized as carriers and vectors of spread of HIV-1 instead of mere links in the broad network of heterosexual transmission. Class distinctions are also related to HIV/AIDS, since poverty increases vulnerability to the infection. Finally, HIV/AIDS is a life threatening illness that people are afraid of contracting. This interacts with other sources of stigma attached to the illness and exacerbates the problem.⁸

⁷ The Commission on Macroeconomics and Health (CMH) estimated that the costs to reach about 70 percent coverage for various prevention activities in all of South Asia would be about US\$0.40 per capita in 2007 and about US\$0.51 per capita in 2015 (Jha and Mills 2002). However, the CMH costs were for an expanded set of activities that did not include universal condom promotion. The CMH estimates are in line with the estimates that exclude condom promotion in Table 5.

⁸ Stigma needs to be dealt with at different levels. First, at the policy and legal level, proper laws and procedures must be in place to ensure that vulnerable groups are adequately protected from discriminatory

Low public awareness and ownership: Raising the levels of awareness of people about the modes of transmission of HIV-1 and the methods of prevention needs to be accorded a high priority under the program, a prerequisite for any eventual vaccination program and for the successful expansion of preventive interventions.

Vaccine delivery infrastructure. While the immunization program in India has accomplished a good deal, with a steady decline in the number of vaccine-preventable diseases being reported, overall program performance has been sub-optimal and uneven across states (World Bank 2000). This has been largely due to an erosion of both human resource and infrastructure capacity. The cold chain, necessary to refrigerate vaccines from procurement to client use, and the transport system have weakened due to aging and inadequate financing. Better coordination is needed among the departments managing the five major components of the program: vaccine production, vaccine quality assurance, service delivery, disease surveillance, and research. As a result, India has been unable to take advantage of the global technological advances that have made available new vaccines, such as hepatitis B. In the absence of national guidelines, states have responded to vaccine-preventable disease with inefficient campaign approaches, as in the case of neonatal tetanus, or by introducing new vaccines on a pilot basis, with insufficient consideration of epidemiological factors, costs, institutional capacity, and sustainability (World Bank 2000).

The public health delivery system. The capacity of the public health system would need to be substantially built up in order to handle an expanded HIV vaccination program. Having well trained field workers in place, especially designated as HIV/AIDS officers, would greatly enhance the effectiveness of the program at the field level. This has been the case in other successful programs that have required intensive community-level intervention such as leprosy elimination, nutrition, and polio eradication. To re-train the network of polio officers, for example, and utilize their services for HIV-1 prevention would be one way of addressing this problem.

Lack of a plan to involve the private sector. Given the size of the private health sector in India and its reach in rural areas, excluding the private sector may severely limit the scope and impact of an HIV vaccination program. In addition, the private sector is believed to be a dominant source of primary treatment of STIs. Involvement of private physicians would help

measures, like compulsory screening and testing, compulsory notification of AIDS cases, and isolation and detention of HIV-1 positive persons. Second, at the institutional level, such practices as pre-employment screening, termination of employment of people living with HIV/AIDS (PLWHA), and denial of treatment and care, must not be allowed to occur. Third, stigma must be dealt with in the community context, as local cultural beliefs and practices may blame the individual for contracting the disease. This could lead to scape-goating, punishment and shunning, particularly of those already suffering from AIDS. In some extreme cases, this has led to AIDS-related murders (recent case in Maharashtra). Finally, stigma must be addressed in the family context, since the family is the major source of care and support. The effect of stigma within the family is most severely experienced by women, who are often rejected by the family and face loss of home and children. The stigmatization can also extend to the larger family of the people living with HIV/AIDS, such as their children and partners.

to enhance the coverage of STI services and provide an opportunity for timely intervention, in particular the syndromic management. Although the immunization program in India requires mainly public sector delivery and financing, the private sector and NGOs have both key roles to play in social mobilization for immunization and in service delivery in areas where the public sector system is weak, in the cities (private sector) and in deprived rural areas (NGOs).

National capacity for vaccine trials. At an operational level, developing countries such as India offer a different set of challenges with respect to vaccine development and field trials. There is a lack of trained investigators (science, clinical trials, ethics, lab, data management, project management) and infrastructure (clinics, labs, equipment, supplies) in place to conduct vaccine trials. The regulatory processes to consider and evaluate proposed experimental vaccine trials are not developed. A formidable challenge in vaccine development is the enormous genetic diversity of HIV-1 found world-wide. Most candidate vaccines are based on HIV clade B, which is only one of more than ten clades and not the one that is dominant in India (NIAID 2000). An ideal vaccine must protect individuals against any genetic subtype of the virus as well as any route of HIV-1 infection. In addition, it was found in Uganda that participants in vaccine trials feared contracting the infection from the vaccine (Mugerwaa and others 2002).

Inadequate funding for HIV prevention. Low funding for vulnerable group interventions is one constraint to high coverage. NACO is currently funded by a World Bank credit of \$191 million over five years. A quarter of this is for targeted interventions to vulnerable groups.⁹ In addition, USAID, the UK Department for International Development (DfID), and the Canadian International Development Agency (CIDA) will provide approximately \$71 million over the same period, mainly focusing on vulnerable groups. All told, this means approximately 2 US cents per capita per year for prevention of HIV in vulnerable groups, or approximately 12 US cents in purchasing power parity terms. In Karnataka, for example, the budget for targeted interventions for the year 2002-03 is about Rs.12,140,000 (US\$245,000), which works out to about 4 US cents per capita. Even with the 20 new interventions planned with an additional expenditure of Rs. 17,200,000 (US\$350,000), this is a woefully inadequate amount to be spending in a state that has an HIV-1 prevalence rate of 1.68percent in ANC sites.

Capacity to design, implement, monitor, and evaluate programs. There is a huge need for capacity building of all levels of workers to design, implement, monitor, and evaluate HIV programs: State AIDS Control Society officers; NGO personnel; field workers; and health workers. Some efforts have worked in different states but they need to be scaled up significantly, and need to be replicated in other states where such initiatives have not yet been undertaken. Current coverage of sentinel surveillance at both ANC sites and STI sites is very

⁹ The current allocation represents an improvement. Under an earlier World Bank credit from 1992-1999, NACO spent about 40 percent of funds on blood safety, 37 percent on general information campaigns, and 7 percent on STI control. Lack of emphasis on vulnerable groups is not unique to India, however.

low (30 percent and 19 percent, respectively). There is no functioning STI surveillance system in place, and no data on either STI or HIV-1 from the private sector, where the majority of service providers operate. Monitoring and evaluation capacity is extremely weak.. The state with the best record is Tamil Nadu, where sentinel surveillance and six waves of behavioral surveillance sponsored by USAID-funded APAC project have successfully tracked the epidemic, levels of awareness, and behavior change. Such data has helped TNSACS to set priorities for focused interventions. Andhra Pradesh and Karnataka are now beginning to benefit from this type of input from the DfID- and CIDA-funded programs in their states, but much more needs to be done.

8. Recommendations

This study gives rise to several recommendations. First, there is a need to more in-depth case studies on the ability and willingness of various vulnerable groups to accept and access a possible HIV-1 vaccine.

Second, there is a need to expand implementation of prevention programs, which will remain critical even if an effective vaccine is eventually available.

Third, the common inputs to vaccines and prevention require considerable strengthening. These include:

- Better surveillance of the trends in HIV-1 by expanding the number and quality of sentinel surveillance among ANC and STI clinic attendees to every district.
- As sentinel surveillance is poor at predicting levels (it is better at detecting changes in prevalence), a few large, longitudinal studies of well-characterized population cohorts of HIV-1 negative people to measure the incidence of HIV-1 (the number of new infections). These are also required to better understand transmission dynamics in different states and thus help inform the relative importance of targeting vaccines.
- Common tools of mapping at local levels (i.e. district or below) of populations who would require preventive interventions, including vaccines.
- Strong human resource development of a cadre of HIV/AIDS officers who can work like the polio officers in India to: conduct surveillance and improve its quality; work and train NGOs to conduct peer group interventions; and strengthen STI syndromic management.
- Ongoing evaluation activities to identify gaps in coverage (for example, continuously providing denominators of “unreached populations” as do immunization programs) and to help monitor any adverse behavior change that could occur from introduction of vaccines and/or availability of anti-retroviral therapies.

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Annex 1. Estimates of the Coverage of Public Health Interventions in Key Groups

Annex Table 1.1. Estimated coverage of CSW interventions

<i>State</i>	<i>Number of CSWs (low est.)</i>	<i>Number of CSWs (high est.)</i>	<i>Number of CSW interventions</i>	<i>Population covered</i>	<i>Coverage (high)</i>	<i>Coverage (low)</i>
Andhra Pradesh	184,208	203,000	17	25,000	14%	12%
Karnataka	127,318	162,000	4	12,000	9%	7%
Maharashtra	228,376	292,000	15	15,000	7%	5%
Tamil Nadu	151,744	212,000	33	33,000	22%	16%
Southern states	691,646	869,000		85,000		

Source: Authors, based on Venkatramana and Sarada (2001)/

Annex Table 1.2. Estimated coverage of trucker interventions

<i>State</i>	<i>Estimated number of Truck drivers^a</i>	<i>Number of trucker interventions</i>	<i>Truckers covered *</i>	<i>Coverage</i>
Andhra Pradesh	358,422	22	110,000	31%
Karnataka	266,724	8	40,000	15%
Maharashtra	525,867	13	65,000	12%
Tamil Nadu	457,131	30	150,000	33%
Southern states	1,608,144	73	365,000	23%

Note: a. Estimated at 3 times the number of trucks registered in 1997.

Source: Authors, based on Automan (2001)

Annex Table 1.3. Number of reported STI cases in public health facilities, 2001

<i>State</i>	<i>Genital ulcer</i>		<i>Urethral discharge</i>		<i>Vaginal discharge</i>	<i>Inguinal swelling^a</i>		<i>Others</i>		<i>Total</i>		<i>Total</i>
	<i>M</i>	<i>F</i>	<i>M</i>	<i>F</i>		<i>M</i>	<i>F</i>	<i>M</i>	<i>F</i>	<i>M</i>	<i>F</i>	
Andhra Pradesh	2,774	655	3,064	492	3,819	344	66	10,920	5,219	17,102	10,251	27,353
Karnataka	1,668	531	1,461	482	7,746	167	35	8,101	3,346	11,397	12,140	23,537
Maharashtra	2,403	791	2,059	1,282	22,211	164	56	6281	11,700	10,907	36,040	46,947
Tamil Nadu	4,821	3,221	4,155	2,244	16,682	1,120	742	20,716	12,993	30,812	35,882	66,694
Southern states	11,666	5,198	10,739	4,500	50,458	1,795	899	46,018	33,258	70,218	94,313	164,531
India	27,348	12,666	24,690	9,542	126,190	2,866	1,446	128,162	80,970	183,006	230,724	413,790

Note: a. Swelling of the groin.

Source: NACO (2002). "Surveillance for STD Cases in India, January 2001 to December 2001". MOHFW, Delhi.

Annex Table 1.4. Percent of Those with an STI Seeking Treatment in a Government Hospital/Clinic during the Last Episode
(n=number who reported STI or symptoms in the last 12 months in the sample)

State	Urban			Rural			Combined ^a		
	Male	Female	Total	Male	Female	Total	Male	Female	Total
Andhra Pradesh	24.2 (62)	28.6 (63)	26.4 (125)	45.8 (83)	23.5 (68)	35.8 (151)	41.1 (155)	24.8 (133)	33.6 (288)
Karnataka	28.6 (14)	18.8 (80)	20.2 (94)	29.7 (37)	13.2 (38)	21.3 (75)	29.6 (60)	15.9 (102)	20.9 (162)
Maharashtra	30.8 (13)	54.8 (73)	51.2 (86)	14.8 (27)	27.3 (55)	23.2 (82)	18.5 (43)	39.8 (124)	34.3 (167)
Tamil Nadu ^b	33.3 (12)	21.1 (19)	25.8 (31)	40.0 (10)	31.6 (19)	34.5 (29)	37.4 (21)	27.9 (38)	31.4 (59)
India (mean)	28.2	24.5	25.6	30.5	18.9	22.7	28.6	19.6	22.4
Standard Deviation	16.9	17.1	14.8	15.6	14.4	12.1	14.9	13.1	12.0
Median	30.8	24.6	26.2	31.7	19.8	24.1	31.6	19.7	25.1
Range	9.7- 75.0	9.1- 75.0	10.6- 68.0	6.7- 60.0	0.0- 65.6	7.7- 56.5	7.1- 64.1	9.6- 57.2	10.0- 58.9
(n)	(490)	(1102)	(1592)	(662)	(1378)	(2040)	(1197)	(2681)	(3878)

Note: a. Weighted figures. b. Tamil Nadu and Pondicherry.

Source : NACO (2001).

Annex Table 1.5. Coverage of Different Vaccines (percent), 1999

State	BCG	DPT1	DPT2	DPT3	OPV1	OPV2	OPV3	Measles	Immunization Status		
									Full	Partial	None
Andhra Pradesh	92.6	95.0	93.4	92.0	94.6	93.4	91.7	78.1	75.7	21.5	2.8
Karnataka	97.5	97.9	97.8	97.0	97.8	97.5	96.7	93.2	91.3	7.4	1.3
Maharashtra	98.2	99.3	97.0	96.2	99.1	96.6	96.0	82.0	79.5	20.1	0.4
Tamil Nadu	97.5	98.8	98.5	97.6	98.7	98.0	97.6	93.6	91.9	6.9	1.2
India	85.9	87.6	84.7	80.8	87.7	85.0	81.0	66.5	63.3	27.1	9.6

Source: Government of India/MOHFW (1999).

Annex Table 1.6. Percent of Currently Married Women using Condoms for Contraception, 1999

Age	State			
	Andhra Pradesh	Karnataka	Maharashtra	Tamil Nadu
15-19	0.2	0.3	1.2	0.5
20-24	1.0	1.0	6.7	1.9
25-29	0.6	1.3	5.4	2.4
30-34	1.7	1.4	5.4	1.8
35-39	0.6	1.6	2.0	1.5
40-44	0.0	0.7	1.9	0.8
45-49	0.0	0.6	0.9	0.0
Total	0.7	1.0	4.0	1.5

Source: NFHS, 1992-93 and 1998-99, from IIPS (1995, 2000).

Annex 2. Estimating the Costs of Additional Coverage (“scaling up”) of HIV Prevention Programs in Southern India

2.1 Targeted interventions to high-risk groups

NACO guidelines for costing interventions, which are largely based on experience in some of the southern states, suggest that the annual cost per person reached is Rs. 1,208.05 per CSW and Rs. 94.7 per truck driver (NACO 1999). Bringing coverage to 100 percent for these two groups would require reaching (approximately) 800,000 additional sex workers (using the high estimates of the number of CSWs in these states) and 1.25 million additional truckers, at a **total annual cost of Rs. 966.8 million (US\$ 19.3 million) for CSW and Rs. 118.4 million (US \$2.4 million) for truckers**. These are the annual *recurrent* costs for the coverage of the *additional* interventions and exclude training or capacity building to NGOs that would be necessary investments in wider implementation.

2.2 STI treatment services

The estimated cost of scaling up an STI control program is based on the costing worked out by the Maharashtra State AIDS Control Society. The cost of raising the number of STI sites per district to two would cost about Rs. 23 million per state or US\$0.5 million in investment costs.¹⁰ This would include the costs of goods (Rs. 1.7 million or US\$300,000); equipment (Rs. 6.9 million or US\$0.15 million); vehicles and furniture (Rs. 1.5 million or US\$0.03 million); and medicines (Rs. 12 million or US\$0.25 million). The recurrent costs per state for these additional STI clinics would be about Rs. 14 million or US\$0.3 million. Together across the four states, this amounts to **investment costs of Rs. 92 million (US\$ 1.8 million) and annual recurrent costs of Rs. 56 million (US\$ 1.1 million) for the additional clinics**.

2.3 Sentinel surveillance

In order to establish a minimum of one sentinel surveillance site in each district, an additional 59 sentinel sites need to be set up. An estimate made by the Karnataka State AIDS Control Society in their Action Plan indicates that an additional sentinel site would cost Rs. 110,000 (honorarium for personnel, transportation, training and equipment). The cost of 59 additional sites would amount to **Rs. 6,490,000 or US\$130,000**.

2.4 Condom distribution

The total population of adults 15-49 in the four states is roughly 140 million, of which roughly half, or 70 million, are men (see Table 2 of the text). If one were to establish the goal of condom use in every sexual act (including universal condom use in marriage, even if one partner is already sterilized) and assuming an average need of 100 condoms per man per year, then the total requirements for condom distribution (through public or private sources) would be 7 billion condoms.

¹⁰ Insuring two STI sites per district would require an additional 23-30 sites per state.

For fiscal year 1999-200, distribution of condoms in the southern states through NACO (including socially marketed condoms and those commercially distributed) is estimated to be 25 percent of the national total of roughly 650 million condoms, or 162.5 million. In addition, about 80 million condoms are distributed free of charge in these states through the Ministry of Health and Family Welfare. This brings the total current distribution to 242.5 million condoms annually.

The shortfall between actual condom distribution and 100 percent coverage is therefore 6.76 billion condoms. At Rs. 4 per condom, the total cost would be about Rs. 27 billion or US\$ 540.6 million a year.

Due to the low usage rates of condoms, the concern is whether the distribution under RCH and AIDS control is enough and whether it should be scaled up to cover all the persons in the target cohort or restricted to a lesser percentage with a suitable effort to increase social marketing and commercial distribution. Over the years, condoms have become associated with family planning, and couples who have chosen more permanent methods such as vasectomy or tubal ligation would not feel it necessary to use condoms. To promote condoms for reasons other than family planning would take a particularly rigorous behavior change communication program aimed at the general population. NACO figures indicate that twice the number of condoms was being socially and commercially marketed in the southern states as was freely distributed, indicating that there is a willingness to pay for condoms among certain segments of the population. However, this may not apply to all segments. These are some of the concerns that need to be addressed.

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